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February 27, 2006

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**BY ELECTRONIC FILING**

The Honorable Kent A. Jordan  
United States District Court  
844 North King Street  
Wilmington, DE 19801

Re: *Biovail v. Andrx Pharmaceuticals LLC et al.*,  
Civil Action Nos. 05-586 (KAJ) (Consolidated)

Dear Judge Jordan:

Plaintiff Biovail hereby responds to Defendant Andrx's February 24, 2006 letter ("Andrx letter") requesting that the Court compel Biovail to supplement its interrogatory responses and produce additional documents. Andrx's letter simply rehashes the same issues that were decided by the Court at the January 26, 2006 discovery conference.

**I. Andrx's Complaints Regarding Biovail's Interrogatory Responses Are Moot**

Fundamentally, Andrx's letter acknowledges that Biovail has always been willing to supplement its interrogatory responses as directed by the Court. That is in stark contrast to Andrx's conduct. Andrx has repeatedly refused Biovail's requests that Andrx promptly supplement its bare-bones contention interrogatory responses regarding its invalidity allegations, apparently believing that Andrx can provide full responses whenever it pleases. (*See* Exh. A, p.3, Andrx's February 17, 2006 letter). As explained in Biovail's February 24, 2006 letter, however, that is contrary to Your Honor's guidance that the parties be forthcoming in providing discovery.

Andrx's complaints regarding the timing of Biovail's supplemental interrogatory responses are apparently designed to obfuscate its own failure to cooperate in discovery. Following the last Court conference, Biovail proposed that the parties exchange supplemental interrogatories responses in accordance with the Court's guidance. (*See* Exh. B, Biovail's February 1, 2006 letter). Rather than engage in a good faith discussion, Andrx's responded by contacting the Court the very next day to request tomorrow's discovery conference, thereby demonstrating its lack of interest in resolving the dispute. (*See* Exh. C, Andrx's February 2, 2006 letter).

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Nevertheless, Andrx's complaints are moot because today Biovail will supplement its interrogatory responses.

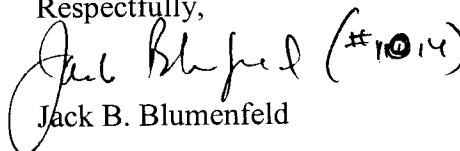
**II. Andrx's Complaints Regarding Biovail's Document Production Lack Merit**

Andrx's complaints regarding Biovail's document production are essentially the same as the scattershot complaints regarding 60 document requests that were before the Court at the January 26, 2006 conference. Andrx raises them again under the guise that the Court "did not have time to expressly address" these issues. (See Andrx letter, p. 3). However, the Court specifically addressed all of the issues raised by Andrx during that conference.

Now, for the first time, Andrx complains that Biovail's document production does not include "testing or analysis of Andrx's products at issue in this litigation." Andrx's complaint lacks merit. Andrx's proposed tableted products are not available on the market, and thus the only way Biovail could gain access to them is through discovery in this litigation. At Andrx's insistence, only Biovail's experts, pursuant to a confidentiality agreement, have been provided samples of Andrx's proposed tableted products. Any testing of Andrx's proposed products by Biovail's experts is immune from discovery until Biovail designates such experts as testifying witnesses, however, see *Moore U.S.A. Inc. v. Standard Register Co.*, 206 F.R.D. 72, 74-75 (W.D.N.Y. 2001). Thus, at this time, no non-immune documents exist.

Andrx also argues that Biovail should produce documents relating to other proceedings involving the '791 patent, including foreign counterparts. Biovail has already produce all of Biovail internal documents that were produced in U.S. patent infringement litigations involving the '791 patent. To the extent that Andrx seeks documents from foreign litigations, documents production of third-parties, and Court submissions, such requests are unduly burdensome as the majority of those papers are subject to confidentiality agreements, and include confidential information of third-parties. Andrx has not explained the relevance of such documents, which involve different products and legal issues.

Respectfully,

 (#1014)  
Jack B. Blumenfeld

/cbn  
Attachment

cc: Peter T. Dalleo, Clerk (By Hand w/Attachment)  
Richard L. Horwitz, Esquire (By Hand and E-Mail w/Attachment)  
Steven A. Maddox, Esquire (By E-Mail w/Attachment)  
Joseph M. O'Malley, Jr., Esquire (By E-Mail w/Attachment)

# EXHIBIT A



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CLIENT/MATTER NUMBER  
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February 17, 2006

**VIA FACSIMILE**

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 Fitzpatrick, Cella, Harper & Scinto  
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 New York, NY 10112-3801

Re: Biovail v. Andrx Pharmaceuticals LLC et al.,  
Civil Action No. 1:05-cv-586

Dear Mr. Ratliff:

We write in response to your February 13, 2006 letter to Steve Maddox regarding Andrx's interrogatory responses and document production. Your mischaracterization of Andrx's statements and positions is unnecessary and unproductive. *First*, your statement that "Andrx's assertion that on the eve of the January 26, 2006 discovery conference, Biovail 'ginned up' discovery complaints in an attempt to deflect attention from an alleged refusal to produce discovery to Andrx is nonsensical as Biovail never even raised its discovery complaints with the Court" is false and inconsistent with the transcript from the January 26, 2006 conference. For example, the Court stated:

THE COURT: Okay. Now help me out with the timing here, too, because your opponent [Andrx] makes the assertion that this is a ginned-up position for you to take in this call. That in the months since they propounded this answer you didn't say boo about it being a problem until the prospect of dealing with the Court on this call came up and then that is when you decided: Well, wait a second, their answer is inadequate and therefore we don't have to answer. I want to give you a chance to go ahead and answer that.

(Transcript of Jan. 26, 2006 hearing ("Transcript"), p. 9, ln. 22 – p. 10, ln. 5).

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In responding to the Court's inquiry, Mr. O'Malley raised its discovery complaints and argued why it believes Andrx's responses are deficient. (Transcript, p. 10, ln. 6 -- p. 11, ln. 11. Notably absent from Mr. O'Malley's response is any indication that Biovail was not at that time raising its discovery complaints with the Court. We request that you refrain from making such false accusations in the future.

*Second*, your allegation that "Andrx ignored Biovail's proposal to exchange supplemental interrogatory responses" is also false. We responded to Biovail's proposal in our February 2, 2006 letter when we informed you that Biovail does not have the right to "dictate conditions upon which it will produce discovery, nor does it have the right to dictate the conditions upon which it will obey the Court's instructions." Interestingly, although Biovail indicated that it was prepared to provide supplemental responses by Monday February 13, 2006 (see February 1, 2006 letter from Preston Ratliff), we have not received Biovail's supplemental responses. It appears that although Biovail was ready to provide Andrx with supplemental responses interrogatories on February 13, 2006, it intends to hold those responses hostage until it can extract concessions from Andrx that it is not entitled to receive.

Biovail's continuing refusal to provide its supplemental responses to interrogatories is a direct violation of the Court's instructions and contrary to law. Indeed, as the Court stated:

But what the law doesn't provide is for you [Biovail] to turn to essentially self-help by saying, you know what, we really don't like your answer so we're not giving you anything that you are asking for in this regard until we like your answer more.

(Transcript p. 11, ln. 21-25).

Further, it is well established that Biovail's conditions upon which it will produce discovery is directly inconsistent with the Federal Rules of Civil Procedure and, thus, has been consistently rejected by courts as utterly baseless and improper. *See* Fed. R. Civ. P. 26(d); *Convolve, Inc. v. Compaq Computer Corp.*, 00 Civ. 5141 (JSM), 2000 WL 1480363, at \*1 (S.D.N.Y. Oct. 6, 2000) ("As Rule 26(d), Fed. R. Civ. P. states, 'methods of discovery may be used in any sequence, and the fact that a party is conducting discovery, whether by deposition or otherwise, shall not operate to delay any other party's discovery.' Under the Federal Rules' liberal discovery regime, without judicial intervention *a party can neither assert priority in discovery nor make its responses to another party's discovery requests contingent upon reciprocal compliance.*" (citing *Burda Media, Inc. v. Blumenberg*, 97 Civ. 7167, 1999 WL 413469, at \*5 (S.D.N.Y. June 21, 1999)) (emphasis supplied).

In light of the well-established law on this issue, Biovail's violation of the Court's instructions, and continuing refusal to provide discovery despite the fact that Biovail was prepared to exchange supplemental responses by February 13, 2006, Andrx reserves the right to seek all appropriate relief from the Court, including sanctions for Biovail's discovery misconduct.



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With respect to the other issues raised in your letter, we address each item in the order in which they were presented:

#### **I. Andrx's Interrogatory Responses**

We understand your reference to Interrogatory No. 1 in your February 13, 2006 letter is based only on the fact that Andrx's response to Interrogatory No. 2 incorporated by reference the invalidity portions in its response to Interrogatory No. 1. Please let us know immediately if our understanding is incorrect because Biovail has not previously raised any complaints regarding Andrx's response to Interrogatory No. 1 with respect to its non-infringement contentions.

Your citation to "hornbook patent law" as the "authority" supporting the level of detail that Biovail seeks and listing what it believes are the elements for the anticipation and obviousness defenses ignores our simple request for Biovail to provide authority for the level of detail you seek *at this stage in the case*. Indeed, as we previously indicated to you, the Court already reviewed our response to Interrogatory No. 2 and determined that it was sufficient *for this stage of the case*. (Transcript p. 12, ln. 5 - 11). Although Andrx's responses are sufficient for this stage of the case, Andrx will continue to comply with the Court's instructions and the Fed. R. Civ. P. 26(e) and supplement its discovery responses, at the appropriate time as additional information becomes available.

Subject to Andrx's objections, it is our understanding that there are no "opinion, study, analysis, report, test, or investigation requested, obtained, and/or conducted by Andrx relating to the infringement or validity of the '791 patent" other than those prepared by counsel, which we have already identified. The opinion of counsel obtained by Andrx relating to the patent-in-suit is obviously privileged and Andrx has not waived the privilege. We note that you have not explained how any of the information Biovail seeks related to the opinion of counsel is relevant to any of the issues in this action in light of the fact that willful infringement is not an issue in this action.

#### **II. Andrx's Document Production**

Andrx has made a reasonably diligent search for responsive documents and, subject to its objections, has already produce all relevant, non-privileged documents responsive to Biovail's requests. Indeed, we note that Andrx has produced over 5 times more pages of documents than Biovail. Nevertheless, we will make another search for (1) reports regarding the development of the formulation of its proposed tableted products, (2) batch records for extended-release pellet lots [REDACTED], [REDACTED], [REDACTED], [REDACTED], and [REDACTED], (3) manufacturing records for the 420 mg. tablet lots [REDACTED], [REDACTED] and for the samples provided on December 30, 2005, and Andrx will produce all relevant, non-privileged documents, if any, to the extent not already produced.

REDACTED

We agree that both parties shall produce supplemental FDA correspondence (Biovail's NDA No. 21-392 and Andrx's ANDA No. 77-686) every two months.



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Andrx has agreed to provide Biovail with all FDA correspondence concerning its ANDA No. 77-686. Indeed, Andrx has already produced those documents to Biovail and will continue to do so pursuant to the parties' agreement to periodically produce supplement FDA correspondence. While the FDA documents concerning Andrx's ANDA No. 77-686 may be relevant to the subject matter of this action, the FDA Form 483 letter concerning manufacturing facilities of Andrx's existing, approved products, is not. Indeed, it is undisputed that Andrx's approved products are not at issue in this litigation. Further, the fact that the "beads" employed in Andrx's proposed unapproved product may be identical in composition to beads in other products not at issue in this litigation does not render all documents related to the approved product not at issue in this action relevant to this litigation. Nevertheless, should the FDA require Andrx to change its manufacturing procedures for its proposed unapproved product, we anticipate that those changes would be reflected in the correspondence with the FDA related to ANDA No. 77-686, which we already stated will be produced.

The only product at issue is the proposed product that is the subject of Andrx's ANDA. The technical documentation concerning that product, including the raw materials, are in the ANDA. Accordingly, Andrx already produced the technical documentation, including the raw materials, related to the sole product at issue. (*See, e.g.*, Section VIII of the ANDA). To the extent that Biovail is seeking technical documentation for products that are not the subject matter of the ANDA, we fail to see the relevance of such technical documentation to the issues in this action.

There has been no failure by Andrx to produce documents regarding its notice letters, organizational charts or document retention, disposal or destruction policies. To the best of our knowledge, after a reasonably diligent search, there are no responsive, non-privileged documents regarding these categories in Andrx's possession, custody or control. Our investigation and discovery is continuing and should we locate any responsive, non-privileged documents, if any, they will be provided.

Although you accuse Andrx for failing to address each of the missing documents identified in Biovail's January 24, 2006 letter, you do not identify any documents that Andrx failed to address. Instead, you improperly shift the burden of identifying documents that Andrx allegedly failed to address to Andrx. We are not clairvoyant and thus cannot determine what you think is missing from our February 3, 2006 letter. Further, it is not our burden to compare the two letters and determine what discovery complaints you think Andrx "failed" to address. If you truly believe that we have not addressed all of the issues raised in your January 24, 2006 letter, identify those issues for us and we will respond, as appropriate.

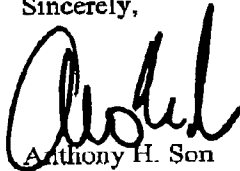
Finally, your threat that Andrx either provide the requested discovery or Biovail will raise "Andrx's discovery failures" with the Court is an ultimatum and not a good faith effort to meet and confer. Although it does not appear that Biovail is genuinely interested in engaging in a good faith meet and confer to resolve its discovery complaints, we are nevertheless available for a meet and confer. Let me know if Biovail would like to meet and confer or if this is another ploy to deflect attention from its discovery misconduct and refusal to produce discovery.

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Concerning your statement that Biovail will raise Andrx's discovery failures with the Court during the February 28, 2006 conference, has Biovail already contacted the Court and scheduled a conference on its discovery complaints for that date? If not, we object to Biovail's attempt to use the time Andrx reserved with the Court to raise its own discovery complaints. As you know, the Court's time is very limited and we refuse to be prejudiced by Biovail's continuous attempts to delay resolution of its discovery misconduct and the issues that the Court did not have the time to address during the January 26, 2006 conference. If a discovery conference becomes necessary to address Biovail's discovery complaints against Andrx, it can request its own dates from the Court.

Sincerely,



Anthony H. Son

cc: Jack Blumenfeld  
Richard Horwitz  
Martin Endres



# EXHIBIT B

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February 1, 2006

VIA FACSIMILE

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Washington, DC 20007-5143

Re: *Biovail v. Andrx Pharmaceuticals LLC et al.*,  
Civil Action No. 1:05-cv-586 (KAJ)

Dear Mr. Maddox:

This is response to Andrx's January 30, 2006 letter regarding Biovail's interrogatories responses, and Biovail's document production.

First, based on the Court's guidance in the January 26, 2006 telephone discovery conference, Biovail proposes that on Monday, February 13, 2006, the parties exchange supplemental interrogatory responses. Biovail will supplement its responses to Andrx Interrogatories Nos. 1 and 4 provided that Andrx agrees to supplement its responses to Biovail Interrogatory Nos. 1 and 2 to include an identification of each claim that Andrx asserts is invalid, and a full and complete explanation of the bases for its assertions. If Andrx maintains that the '791 patent is invalid under 35 U.S.C. § 102, please include a detailed explanation of how each element of the '791 patent claims is disclosed by the prior art, and if Andrx maintains that the '791 patent is invalid under 35 U.S.C. § 103, please include a detailed explanation of: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claims and the prior art; and (4) why the differences between the claims and the prior art would have been obvious. Further, Biovail requests that Andrx also supplement its response to Biovail Interrogatory No. 3 to include all of the missing information identified in Biovail's January 24, 2006 letter.

Second, Biovail is not in a position to supplement its response to Andrx Interrogatory No. 6 by this Friday, because it is just now exploring what evidence is available regarding unexpected properties and/or secondary considerations. Biovail will let

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Andrx know whether it has elected to rely on such evidence by Friday, February 17, 2006, and if so, it will supplement its response to Interrogatory No. 6 within three business days thereafter, and will commence production of pertinent documents.

Third, Andrx suggests in its letter that it already reproduced the Andrx production that Biovail requested from the Tiazac® litigation, and thus contends that Biovail should immediately produce the Biovail production from the Tiazac® litigation that Andrx requested. Please identify, by bates number, where each of the documents requested in Tab A of Biovail's December 28, 2005 letter can be found, and Biovail will promptly produce the Biovail production that Andrx requested to the extent that it has retained those documents.

Finally, the lack of merit of Andrx's other complaints is evident by the fact that the Court did not even address those issues during the discovery conference. Biovail's January 26, 2006 letter to the Court set forth its position on those issues, and Andrx's letter does not provide any substantive response -- it simply regurgitates the same unsupported complaints raised in Andrx's January 25, 2006 letter to the Court. Of Andrx's myriad of complaints, the Court chose only to address the issue of documents related to unexpected properties and/or secondary considerations.

Very truly yours,

A handwritten signature in black ink, appearing to read "Preston K. Ratliff II". The signature is stylized with a large, bold "P" and "R", and a clear "II" at the end.

Preston K. Ratliff II

cc: Via Facsimile

Jack B. Blumenfeld, Esq.  
William J. Cattie, III, Esq.  
Martin P. Endres, Esq.  
Herschel Sparks, Esq.

# EXHIBIT C



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CLIENT/MATTER NUMBER  
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February 2, 2006

Preston K. Ratliff, Esq.  
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New York, NY 10112-3801

Re: Biovail v. Andrx Pharmaceuticals LLC et al.,  
Civil Action No. 1:05-cv-586

Dear Mr. Ratliff:

I write in response to your letter of February 1, regarding Biovail's intentions with respect to the discovery issues Andrx raised with you in letters of December 30, 2005, and January 3, 2005 -- and then presented to the Court in Andrx's letter of January 25, 2006, for the conference held on January 26, 2006.

It is apparent that Biovail has no intention of producing much of the discovery that we have been seeking since December 30, 2006 -- both with respect to issues that the Court expressly addressed, and issues that the Court did not have the time to address.

Accordingly, we have contacted Judge Jordan's chambers and requested a second conference with respect to the issues presented in of letter of January 25, 2006. The Court has offered three dates and times; (1) February 24<sup>th</sup> at 9:30 am, (2) February 27<sup>th</sup> at 4 pm, and February 28<sup>th</sup> at 3 pm. We propose February 24<sup>th</sup> at 9:30, and request that you agree to this soonest date in order to expedite resolution of the issues. The Court requested that we get back to it as soon as possible with the agreed-upon date.

With respect to the issues specifically addressed by the Court, your position seems to be that Biovail will do what the Court ordered, but only if Andrx meets certain conditions set by Biovail. This is not how it works. Biovail does not get to dictate conditions upon which it will produce discovery, nor does it have the right to dictate the conditions upon which it will obey the Court's instructions.



Preston K. Ratliff, III, Esq.  
February 2, 2006  
Page 2

For instance, your obligation to produce relevant documents from the prior litigation is not conditioned upon our identifying any documents in our production by Bates number. While we reserve the right to seek a finding of contempt based on such outrageous behavior, we happen to have the information handy, and so have provided it in Attachment A to this letter.

Regarding the alleged discovery issues that you failed to raise until the eve of the Court conference, in your letter of January 24<sup>th</sup>, we will provide a specific responses by letter tomorrow. We continue to believe, and expect to present evidence, that you affirmatively misled the Court as to the timing of those alleged issues. In any event, if you remain unsatisfied with our responses to these alleged "issues," you of course can request your own conference.

Very Truly Yours,

A handwritten signature in black ink, appearing to read 'Steven Maddox', written over a horizontal line.

Steven Maddox

cc: Jack Blumenfeld  
William Cattie  
Martin Endres